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Ophthalmic implants — Intraocular lenses —

Part 8: Fundamental requirements

Implants ophtalmiques — Lentilles intraoculaires —

Partie 8: Exigences fondamentales

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-8:2006), which has been technically revised. It also incorporates the Amendment ISO 11979-8:2006/Amd 1:2011.

A list of all the parts in the ISO 11979 series can be found on the ISO website.

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Ophthalmic implants — Intraocular lenses —

Part 8:
Fundamental requirements

1 Scope

This document specifies fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 11979-9[1)], *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

1) ISO 11979-7 is under revision. The revised standard will incorporate multifocal intraocular lenses. When the revised standard is published, ISO 11979-9 will be withdrawn.

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4 Safety and performance

The safety and performance of an intraocular lens shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis in accordance with ISO 14971.

In cases where a test method referenced in this document is not suitable for a certain design or a certain application, an alternative test method devised by the manufacturer shall be validated, justified and documented.

5 Optical and mechanical properties

The manufacturer shall ensure that the intraocular lens conforms to applicable requirements in ISO 11979-2, ISO 11979-3, ISO 11979-9 and ISO 11979-10. The manufacturer shall record and justify any deviations from those standards.

6 Biocompatibility

The manufacturer shall have documented evidence that demonstrates the intraocular lens to be biocompatible by assessment in accordance with ISO 11979-5.

Manufacturers can take into consideration previous experience and data when determining the extent of further biocompatibility testing.

7 Clinical evaluation

The first step in the clinical evaluation is a review of the available literature (published and unpublished) in order to determine if that information is sufficient to demonstrate the safety and performance of the device (see ISO 14155). One option is to demonstrate that the new intraocular lens model is a minor modification of a model, the safety and performance of which has previously been demonstrated.

NOTE ISO/TR 22979 provides a framework for assessment whether or not a modification is minor.

If the clinical evaluation identifies the need for a clinical investigation, the requirements of ISO 14155 shall apply. In addition, the following standards apply depending on the type of the intraocular lens:

a) ISO 11979-7 for monofocal intraocular lenses for the correction of aphakia;

b) ISO 11979-9 for multifocal intraocular lenses for the correction of aphakia;

c) ISO 11979-10 for phakic monofocal intraocular lenses.

8 Manufacturing

Intraocular lenses shall be manufactured in such a way that the specified design attributes are achieved.

9 Sterilization

9.1 General

Intraocular lenses shall be supplied sterile. Sterilization shall adhere to the general provisions laid out in ISO 14630.

For sterilization by ethylene oxide (EO), the following applies:

a) for the assay of EO residues, an exhaustive solvent or head space extraction method shall be chosen;

b) the residue of EO in intraocular lenses shall not exceed 0,5 µg EO per lens per day, or 1,25 µg per lens;

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c) the residue of ethylene chlorohydrin shall not exceed a release of more than 2,0 µg per lens per day and not exceed 5,0 µg in total per lens.

For solvent extraction, a solvent affording exhaustive extraction shall be chosen, e.g. one that adequately swells the lens material without disrupting the material itself. For headspace extraction, efficiency of extraction shall be demonstrated by validation against an exhaustive solvent extraction method. In case the extraction is not exhaustive, release criteria shall be lowered in proportion to the relative efficiency of the method.

NOTE The level of ethylene glycol is correlated to the levels of ethylene oxide and ethylene chlorhydrin present. If the levels of ethylene oxide and ethylene chlorhydrin are within the limits set in b) and c), the level of ethylene glycol will be sufficiently low that there is no need to quantify it.

9.2 Bacterial endotoxins

The level of biological contamination shall be determined using a validated method for bacterial endotoxin testing in accordance with applicable pharmacopoeia.

The endotoxin level shall, on average, be 0,2 endotoxin units or less per lens. Lenses shall be extracted with endotoxin-free water, and the test method and number of lenses per volume of water shall be chosen such that the test is sufficiently accurate to ensure this level.

10 Packaging and shelf-life

The packaging shall meet the requirements of ISO 11979-6.

NOTE National and regional regulations can impose additional requirements.

11 Labelling and information

The intraocular lens as marketed shall be supplied with labelling and information in accordance with ISO 11979-4.

NOTE National and regional legislation can require additional labelling and information.

12 Documentation

All primary data, calculations, results and reports shall be documented and kept on file by the manufacturer for as long as required by regulations.

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Bibliography

[1] ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

[2] ISO/TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

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